



**DEPARTMENT  
OF  
HEALTH PROFESSIONS**  
6603 W. BROAD ST, 5<sup>th</sup> FLOOR  
RICHMOND, VA 23230

# COMPOUNDING STERILE PHARMACEUTICAL PRODUCTS INSPECTION REPORT

Facility Name:

Facility License No:

Date:

Rev: 091603

Section No Regulation No.	AREA/QUESTION	COMPLIANCE		Section No Regulation No.	AREA/QUESTION	COMPLIANCE	
		YES	NO			YES	NO
<b>POLICY AND PROCEDURE MANUAL</b>				<b>PHYSICAL &amp; EQUIPMENT REQUIREMENTS</b>			
110-20-412.1	Personnel qualifications including initial and follow-up training and method of periodic re-evaluation of qualifications & performance?			110-20-413 D	Adequate supplies, including:		
				110-20-413 D	Antimicrobial soap?		
110-20-412.2	Scope of compounding performed at the pharmacy and proper procedures for compounding to include maintaining suitable environmental conditions in the compounding area, wearing appropriate garb to reduce particulate matter and contamination of work area, performing aseptic procedures.			110-20-413 D	Easily accessible hot and cold water?		
				110-20-413 D	Appropriate apparel?		
				110-20-413 D	Suitable disposal containers?		
110-20-412.3	Procedures for maintaining and monitoring proper operating conditions for all equipment used in sterile compounding?			110-20-413 E	Current reference materials?		
				110-20-413 F	Appropriate temperature for drug storage and delivery?		
110-20-412.4	Guidelines for patient or caretaker education if products are dispensed for home use to include instructions concerning proper storage, aseptic manipulation of the product, proper administration and use of devices if applicable, recognizing signs of instability or incompatibility, and procedures in case of an emergency with the product?			<b>LABELING REQUIREMENTS</b>			
				110-20-414 A	Labeling includes all active ingredients and solutions, strengths, amounts, and concentrations? Includes name of all solutions if for IV infusion?		
				110-20-414 B-C	Appropriate beyond-use date and time for parenteral and other compounded sterile products? In accordance with regulation if not specified and justified in policy & procedure manual?		
110-20-412.5	Guidelines for assignment of beyond-use date and justification for any date chosen which exceeds standard in regulation?			110-20-414 D	Appropriate administration directions for home or out-patient use?		
110-20-412.6	Separate procedures for handling cytotoxic drugs, if applicable to include protective apparel; disposal procedures consistent with applicable local, state, and federal requirements; procedures for handling spills; special packaging and labeling requirements, and delivery procedures to minimize risks of accidental spills?			<b>STERILE COMPOUNDING RECORDS</b>			
				110-20-416 (1)	Compounding records include:		
110-20-412.7	Separate procedures for compounding sterile products using non-sterile components or open system transfer techniques and for end-product sterilization of these products if applicable?			110-20-416 (1)	a. Date of sterile compounding?		
				110-20-416 (1)	b. Beyond-use date assigned to product?		
				110-20-416 (1)	c. Signature or initials of pharmacist and technician, if applicable?		
<b>PHYSICAL &amp; EQUIPMENT REQUIREMENTS</b>				110-20-416 (3)	Records documenting administration training for out-patient use?		
110-20-413 A	Sufficient size of sterile compounding area			Comments (Continue on additional page if required):			
110-20-413 B	Parenteral compounding isolated?						
110-20-413 C	Sterile compounding performed in laminar flow hood in at least Class 100 conditions?						
110-20-413 C	Cytotoxic compounding performed in vertical flow Class II biological safety cabinet?						
110-20-415 B	Hoods certified at least every six months?						

This facility has been inspected by an inspector of the Department of Health Professions. The results of the inspection have been noted. I acknowledge that the noted conditions have been deemed by the inspector as not being in compliance and have been explained to me and that I have received a copy of the inspection report.

Signature of Inspector

Date

Signature of Pharmacist

Date